United States Court of Appeals
FOR THE EIGHTH CIRCUIT

No. 04-3117

In re: St. Jude Medical, Inc., Silzone Heart Valve Products Liability Litigation _____ Lester Grovatt; Beatrice Bailey; Levy D. Redden; Bonnie L. Sliger; Joe W. Sanchez, on behalf of themselves and all others similarly situated, Appellees, v. St. Jude Medical, Inc., Appellant, _____ Product Liability Advisory Council, Incorporated; Minnesota Chamber of Commerce, Amicus on Behalf of Appellant.	*	Appeal from the United States District Court for the District of Minnesota.

State of Minnesota; Public Citizen, *
Public Citizen, Incorporated; *
Minnesota Trial Lawyers Association, *
*
Amicus on Behalf of Appellees. *

Submitted: June 20, 2005
Filed: October 12, 2005

Before RILEY, BOWMAN, and BENTON, Circuit Judges.

RILEY, Circuit Judge.

St. Jude Medical, Inc. (SJM) produced the Silzone prosthetic heart valve. A test conducted by SJM showed a slightly higher risk of paravalvular leaks at the site where the valves were implanted. SJM thereafter recalled all unimplanted Silzone valves. Numerous suits were then filed across the nation, and the cases were later consolidated in Minnesota. On motions by the plaintiffs, the district court issued three orders that collectively had the result of certifying two subclasses–one seeking damages based on Minnesota's consumer protection statutes, and another seeking primarily injunctive relief. SJM appeals these two class certifications. We reverse and remand.

I. BACKGROUND

SJM received approval from the Food and Drug Administration (FDA) for the Silzone Heart Valve. The valve had as a unique characteristic a sterile, antimicrobial silver coating on the valve's polyester sewing cuff where the valve connected to a patient's heart tissue. Months after receiving FDA approval, SJM sponsored a random, controlled study comparing patient experience with Silzone- and non-Silzone-coated heart valves. The study data showed a statistically significant 2%

increase for patients implanted with Silzone-coated valves over those implanted with non-Silzone-coated valves in the incidence of paravalvular leaks severe enough to require valve explantation.

SJM immediately recalled all unimplanted Silzone valves. Following the recall, plaintiffs sued SJM in courts across the nation. The cases were consolidated for pretrial proceedings in Minnesota pursuant to the Judicial Panel on Multidistrict Litigation. Eventually, five plaintiffs filed a consolidated amended class action complaint, claiming to represent over 11,000 Silzone valve recipients. The plaintiffs alleged common law strict liability, breach of implied and express warranties, negligence and medical monitoring, and claims under various Minnesota consumer statutes–the False Advertising Act, the Consumer Fraud Act, the Unlawful Trade Practices Act, and the Uniform Deceptive Trade Practices Act. The plaintiffs moved for class certification of an injunctive class, called the "medical monitoring class," and a personal injury class seeking money damages, although both classes made many of the same claims under the same legal theories noted above. The district court found both proposed classes met the threshold requirements of Federal Rule of Civil Procedure 23(a), then conditionally certified the common-law claims in both classes under Rule 23(b)(3) and (c)(4). The court also conditionally certified the medical monitoring class under Rule 23(b)(2) and (c)(4). Finally, the court concluded common issues of law and fact predominated over plaintiffs' claims under Minnesota's consumer protection and deceptive trade practices acts, and a class action was the superior method to adjudicate those claims. The court unconditionally certified a consumer protection class under those statutes pursuant to Rule 23(b)(3).

As to the common law claims, the district court "envision[ed] a minimal number of subclasses, and [found] that only significant variations in state law will be sufficient to require different subclasses," then requested briefing from the parties with regard to subclasses in the conditionally certified classes. After receiving briefing, the court decertified the personal injury class, citing Erie Railroad v.

Tompkins, 304 U.S. 64, 78-80 (1938), and Castano v. American Tobacco Co., 84 F.3d 734, 740-41 (5th Cir. 1996), wherein the Fifth Circuit reversed a district court's class certification order because the district court failed to consider how the variations in state law would affect predominance and superiority. The district court found no two states' laws were substantially alike, which, in the court's estimation, would require management of at least 25 subclasses. The court again conditionally certified the medical monitoring class, subject to the plaintiffs submitting to the court the identities of suitable class representatives and a manageable trial plan. After reviewing the laws of different states with regard to medical monitoring, the court observed it would apply the medical monitoring law of different states, conditionally certifying the class only as to "those plaintiffs whose valves were implanted in states that recognize a stand-alone cause of action for medical monitoring, absent proof of injury." The court concluded the elements of medical monitoring claims in states that recognize such claims "appear[ed] to be the same." In a third order, the court added plaintiffs from more states (for a total of 17) to the list of those presenting medical monitoring claims. Following the third order, two certified subclasses remain: the class based on Minnesota's consumer protection statutes, and the medical monitoring class.

II. DISCUSSION

"We review a district court's ruling granting or denying class certification for abuse of discretion." Glover v. Standard Fed. Bank, 283 F.3d 953, 959 (8th Cir. 2002). "The district court's rulings on issues of law are reviewed de novo, and the court abuses its discretion if it commits an error of law." Blades v. Monsanto Co., 400 F.3d 562, 566 (8th Cir. 2005) (citing Emery v. Hunt, 272 F.3d 1042, 1046 (8th Cir. 2001)) (italics removed). "Thus, even under the abuse of discretion standard, a district court's rulings on issues of law are reviewed de novo." Emery, 272 F.3d at 1046.

To be certified as a class, plaintiffs must meet all of the requirements of Rule 23(a) and must satisfy one of the three subsections of Rule 23(b).[1] Amchem Prods., Inc. v. Windsor, 521 U.S. 591, 614 (1997); Blades, 400 F.3d at 568-69. The Rule 23(a) requirements for class certification are: (1) the putative class is so numerous that it makes joinder of all members impractical; (2) questions of law or fact are common to the class; (3) the class representatives' claims or defenses are typical of the claims or defenses of the class; and (4) the representative parties will fairly and adequately protect the interests of the class. Fed. R. Civ. P. 23(a). The district court certified the class based on Minnesota's consumer protection statutes using Rule 23(b)(3), which provides that a class action may be maintained if the court finds the questions of law or fact common to members of the class predominate over the questions affecting only individual class members, and a class action is the superior method for fair and efficient adjudication of the dispute. The district court certified the medical monitoring class under Rule 23(b)(2), which provides a class action is appropriate if "the party opposing the class has acted or refused to act on grounds generally applicable to the class, thereby making appropriate final injunctive relief or corresponding declaratory relief with respect to the class as a whole."

A. Consumer Protection Class

The district court concluded it would apply Minnesota law to the consumer protection statutes class because the Minnesota statutes permit "any person" to bring suit thereunder. The court conducted a cursory conflict-of-laws analysis as to the application of the Minnesota consumer protection statutes. The court concluded applying Minnesota law was proper because the parties, particularly SJM, had significant contacts with Minnesota, including SJM being headquartered in

[1]Rule 23 was amended in 2003, but those amendments have no bearing on our analysis of this appeal. Class Action Fairness Act of 2005, Pub.L. 109-2, § 7, 119 Stat. 13.

Minnesota, and the fact that "much of the conduct relevant" to the claims "occurred or emanated from Minnesota."

SJM makes numerous assertions of error regarding the district court's order certifying the consumer protection class. SJM argues the U.S. Constitution does not permit a nationwide personal injury class action using the consumer protection law of one state to the exclusion of all other states. SJM claims the nationwide class violates the Constitution's Commerce Clause, the Due Process Clause, the Full Faith and Credit Clause, the Erie doctrine, and the Rules Enabling Act. SJM also argues the nationwide consumer protection class violates Federal Rule of Civil Procedure 23, questioning the manageability of the class, the adequacy of the class representatives, and the typicality of their claims. Finally, SJM argues the plaintiffs cannot meet the predominance or superiority requirements of Rule 23(b)(3).

Addressing the class certification issues only with regard to the Due Process and Full Faith and Credit Clauses, we conclude the district court did not conduct a sufficient conflicts-of-law analysis. The due process and full faith and credit issues "are dispositive, and we believe it prudent not to decide issues unnecessary to the disposition of the case," especially given the numerous constitutional issues implicated in such an analysis. See Georgine v. Amchem Prods., Inc., 83 F.3d 610, 623 (3d Cir. 1996), aff'd sub nom., Amchem Prods., Inc. v. Windsor, 521 U.S. 591 (1997).

The district court's class certification was in error because the district court did not conduct a thorough conflicts-of-law analysis with respect to each plaintiff class member before applying Minnesota law. The Supreme Court has held an individualized choice-of-law analysis must be applied to each plaintiff's claim in a class action. Phillips Petroleum Co. v. Shutts, 472 U.S. 797, 822-23 (1985). There is, of course, no constitutional injury to out-of-state plaintiffs in applying Minnesota law unless Minnesota law is in conflict with the other states' laws. Therefore, we

must first decide whether any conflicts actually exist. See id. at 816. The district court certified a class of over 11,000 Silzone valve recipients, assumedly residing in numerous states. We deem it unnecessary here to review each state's consumer protection laws, and rather rely on our sister circuit's conclusion that "[s]tate consumer-protection laws vary considerably, and courts must respect these differences rather than apply one state's law to sales in other states with different rules." In re Bridgestone/Firestone, Inc., 288 F.3d 1012, 1018 (7th Cir. 2002).

"[F]or a State's substantive law to be selected in a constitutionally permissible manner, that State must have a significant contact or significant aggregation of contacts, creating state interests, such that choice of its law is neither arbitrary nor fundamentally unfair." Allstate Ins. Co. v. Hague, 449 U.S. 302, 312-13 (1981). Here, we cannot determine whether the district court's choice of Minnesota law was arbitrary or unfair, because the court did not analyze the contacts between Minnesota and each plaintiff class member's claims. Application of Minnesota law to all plaintiffs' claims ultimately may be proper, although we suspect Minnesota lacks sufficient contacts with all the parties' claims, and the different states have material variances between their consumer protection laws and Minnesota's. There is no indication out-of-state parties "had any idea that [Minnesota] law could control" potential claims when they received their Silzone-coated valves. Phillips Petroleum, 472 U.S. at 822. Regardless, protection of out-of-state parties' constitutional rights requires an inquiry into their claims' contacts with Minnesota and their individual state laws before concluding Minnesota law may apply.

The district court justified its decision not to conduct a conflicts analysis by relying on section 8.31 of the Minnesota Statutes. This section permits "any person injured by a violation of" Minnesota's consumer protection statutes to bring suit. Minn. Stat. § 8.31, subd. 3a. The court also cited statutory language allowing "[a] person likely to be damaged by a deceptive trade practice" to seek injunctive relief. Minn. Stat. § 325D.45, subd. 1. The court reasoned these statutes permit out-of-state

plaintiffs to bring suit under Minnesota law, and "[t]he fact that individual plaintiffs hail from other states is immaterial," relying on Group Health Plan, Inc. v. Philip Morris Inc., 621 N.W.2d 2 (Minn. 2001), and In re Lutheran Brotherhood Variable Insurance Products Co. Sales Practices Litigation, 201 F.R.D. 456, 461 n.1 (D. Minn. 2001). In Group Health, the Minnesota Supreme Court addressed the question whether "a private plaintiff [must] be a purchaser of the defendant's products in order to properly plead a claim under Minnesota's misrepresentation in sales statutes, Minn. Stat. §§ 325F.67, 325F.69, subd. 1, 325D.13 (2000), and Minn. Stat. § 8.31, subd. 3a (2000)." 621 N.W.2d at 4. The plaintiffs were all Minnesota companies, thus the court did not consider the extraterritorial application of the "any person" language contained in the statutes. Instead, the court considered only who had standing to sue under the statutes, i.e., "individual consumers" rather than "sophisticated purchasers." Id. at 8-9. Lutheran Brotherhood cited Group Health to conclude "any person" meant the Minnesota consumer protection law could be applied to a nationwide class. 201 F.R.D. at 461 n.1. Lutheran Brotherhood's citation to Group Health was misplaced because Group Health spoke only to standing rather than extraterritorial application to a nationwide class.

The district court essentially attempted to preempt the Due Process and Full Faith and Credit Clauses with state standing statutes. This opposes basic constitutional law and is error. See U.S. Const., art. VI, cl. 2; Brooks v. Howmedica, Inc., 273 F.3d 785, 792 (8th Cir. 2001) ("State law which conflicts with federal law is preempted under the Supremacy Clause of the Constitution.") State consumer protection standing statutes do not extinguish federal constitutional rights or relieve courts from performing the analysis required to safeguard those rights. We therefore conclude the district court should have conducted the proper choice-of-law analysis, Phillips Petroleum, 472 U.S. at 822-23, and we reverse and remand for that analysis.

B. Medical Monitoring Class

SJM also asserts the district court erred in certifying the medical monitoring class. SJM argues this class defies Erie's command that federal courts refrain from altering or creating new state law. SJM further argues certification of this class as one seeking injunctive relief under Rule 23(b)(2) violates the Due Process Clause. Finally, SJM argues certification of this class is improper due to diverse legal and factual issues that would make a classwide trial inefficient and unmanageable. We conclude the diverse legal and factual issues preclude class certification, and we reverse on this ground. As this ground again is dispositive, we do not address the Erie and due process arguments.

Class certification under Rule 23(b)(2) is proper only when the primary relief sought is declaratory or injunctive. Although Rule 23(b)(2) contains no predominance or superiority requirements, class claims thereunder still must be cohesive. Barnes v. Am. Tobacco Co., 161 F.3d 127, 143 (3d Cir. 1998). Because "unnamed members are bound by the action without the opportunity to opt out" of a Rule 23(b)(2) class, even greater cohesiveness generally is required than in a Rule 23(b)(3) class. Id. at 142-43. A "suit could become unmanageable and little value would be gained in proceeding as a class action . . . if significant individual issues were to arise consistently." Id. (citation and quotation omitted); see also Lemon v. Int'l Union of Operating Eng'rs, 216 F.3d 577, 580 (7th Cir. 2000) (same). "At base, the (b)(2) class is distinguished from the (b)(3) class by class cohesiveness . . . . Injuries remedied through (b)(2) actions are really group, as opposed to individual injuries. The members of a (b)(2) class are generally bound together through 'preexisting or continuing legal relationships' or by some significant common trait such as race or gender." Holmes v. Cont'l Can Co., 706 F.2d 1144, 1155 n.8 (11th Cir. 1983) (citation and quotation omitted).

Proposed medical monitoring classes suffer from cohesion difficulties, and numerous courts across the country have denied certification of such classes. See,

e.g., Ball v. Union Carbide Corp., 385 F.3d 713, 727-28 (6th Cir. 2004); Zinser v. Accufix Research Inst., Inc., 253 F.3d 1180, 1195-96, amended, 273 F.3d 1266 (9th Cir. 2001); Barnes, 161 F.3d at 143-46; Boughton v. Cotter Corp., 65 F.3d 823, 827 (10th Cir. 1995). Quoting the Third Circuit, the Supreme Court in Windsor listed some of the individual variations precluding class certification: "[Exposure-only plaintiffs] will also incur different medical expenses because their monitoring and treatment will depend on singular circumstances and individual medical histories." 521 U.S. at 624 (quoting Georgine, 83 F.3d at 626). Differences in state laws on medical monitoring further compound these disparities. See id.

In this case, like in Windsor, each plaintiff's need (or lack of need) for medical monitoring is highly individualized. Every patient in the 17-state class who has ever been implanted with a mechanical heart valve already requires future medical monitoring as an ordinary part of his or her follow-up care. A patient who has been implanted with the Silzone valve may or may not require additional monitoring, and whether he or she does is an individualized inquiry depending on that patient's medical history, the condition of the patient's heart valves at the time of implantation, the patient's risk factors for heart valve complications, the patient's general health, the patient's personal choice, and other factors. The plaintiffs concede the states recognizing medical monitoring claims as a separate cause of action have different elements triggering culpability. Simply put, the medical monitoring class presents a myriad of individual issues making class certification improper. For the same reasons the district court decertified the personal injury tort class, the medical monitoring class was certified incorrectly.

Bolstering our conclusion is the fact the plaintiffs never demonstrated to the district court they "would sue for the medical monitoring program sought here even in the absence of a claim for damages." In re Rezulin Prods. Liab. Litig., 210 F.R.D. 61, 73 (S.D.N.Y. 2002). As the Southern District of New York ruled, a district court certifying a medical monitoring class must be satisfied

> that a reasonable plaintiff, based on a medical and economic calculus, would have sued solely for a medical monitoring program, not merely that a lawyer could have been found who would have located a plaintiff and brought a class action in the hope of a fee, else the test would be meaningless.
>
> Plaintiffs have not persuaded the Court that this criterion has been satisfied here. Neither the American Diabetes Association nor the American Association of Clinical Endocrinologists, which promulgate guidelines for the care and treatment of diabetics, nor any public health agency or professional medical society or institution, has recommended special monitoring for patients who formerly took Rezulin.

Id. While every mechanical heart valve patient will require follow-up care in connection with the implant, the question of additional monitoring above that required for normal mechanical heart valve implantation is not clear.

For the above reasons, we conclude class certification of the medical monitoring class was an abuse of discretion. We reverse the district court's certification of this class.

III. CONCLUSION

For the foregoing reasons, we reverse and remand for further proceedings consistent with this opinion.
